



Medical Necessity Criteria for Leukotriene Modifiers

Drug Class - Leukotriene Modifiers. This drug class includes two leukotriene inhibitors, Accolate (zafirlukast) and Singulair (montelukast), and the 5-lipoxygenase inhibitor Zflo (zileuton).

Background – After evaluating the relative clinical and cost effectiveness of the leukotriene modifiers, the DoD P&T Committee recommended that zileuton (Zflo) be designated as non-formulary. This recommendation has been approved by the Director, TMA.

Effective Date: 16 January 2008

Patients currently using Zflo may wish to ask their doctor to consider a formulary alternative.

Special Notes:

1. Active duty cost share always \$0 in all points of service for all three tiers; Active duty cost share always \$0 in all points of service for all three tiers; TRICARE does not cover non-formulary medications for active duty service members unless they are determined to be medically necessary.
2. MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) a MTF provider writes the prescription, and 2) medical necessity is established for the non-formulary medication. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred, as long as medical necessity has been established.

Medical Necessity Criteria for Zflo (zileuton)

The non-formulary cost share for Zflo may be reduced to the formulary cost share IF one or more of the following criteria are met:

1. Use of BOTH of the formulary leukotriene modifiers is contraindicated: Singulair (montelukast), Accolate (zafirlukast).
2. The patient has experienced significant adverse effects from BOTH of the formulary leukotriene modifiers: Singulair (montelukast), Accolate (zafirlukast).
3. Use of BOTH of the formulary leukotriene modifiers has resulted in therapeutic failure: Singulair (montelukast), Accolate (zafirlukast).
4. The patient previously responded to Zflo and changing to a formulary leukotriene modifier would incur an unacceptable clinical risk (e.g., asthma patients stabilized on Zflo).

Criteria approved through the DoD P&T Committee process August, 2007

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TRICARE Pharmacy Program Medical Necessity Form for Leukotriene Modifiers, (Zyflo and Zyflo CR)



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This form applies to the TRICARE Pharmacy Program (Tpharm). The medical necessity criteria outlined on this form also apply at Military Treatment Facilities (MTFs). The form must be completed and signed by the prescriber.

- Leukotriene modifiers on the DoD Uniform Formulary include Singulair (montelukast) and Accolate (zafirlukast). **Zyflo (zileuton) and Zyflo CR (zileuton extended-release) are non-formulary, but available to most beneficiaries at the non-formulary cost share.**
- The purpose of this form is to provide information that will be used to determine if the use of Zyflo or Zyflo CR *instead of a formulary medication* is medically necessary. If Zyflo or Zyflo CR is determined to be medically necessary, non-Active duty beneficiaries may obtain it at the formulary cost share.
- TRICARE will not cover Zyflo or Zyflo CR for Active duty service members unless it is determined to be medically necessary *instead of a formulary medication*, in which case it will be available to Active duty service members at no cost share.

MAIL ORDER and RETAIL	<ul style="list-style-type: none">The provider may call: 1-866-684-4488 or the completed form may be faxed to: 1-866-684-4477The patient may attach the completed form to the prescription and mail it to: Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954 or email the form only to: TpharmPA@express-scripts.com	MTF	<ul style="list-style-type: none">Non-formulary medications are available at MTFs only if both of the following are met:<ul style="list-style-type: none">The prescription is written by a military provider or, at the discretion of the MTF, a civilian provider to whom the patient was referred by the MTF.The non-formulary medication is determined to be medically necessary.Please contact your local MTF for more information. There are no cost shares at MTFs.
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Step 1 Please complete patient and physician information (Please Print)

1	Patient Name: _____	Physician Name: _____
	Address: _____	Address: _____
	Sponsor ID # _____	Phone #: _____
	Date of Birth: _____	Secure Fax #: _____

Step 2 1. Please explain why the patient cannot be treated with a formulary alternative:

2 Please indicate which of the reasons below (1-4) applies to each of the formulary alternatives listed in the table. You **MUST** circle a reason **AND** supply a specific written clinical explanation for **EACH** formulary alternative.

Formulary Alternative	Reason	Clinical Explanation
Singulair (montelukast)	1 2 3 4	
Accolate (zafirlukast)	1 2 3 4	

Acceptable clinical reasons for not using a formulary alternative are:

- Use of the formulary alternative is contraindicated (e.g., due to hypersensitivity).
- The patient has experienced significant adverse effects from the formulary alternative.
- Use of the formulary alternative has resulted in therapeutic failure.
- The patient previously responded to Zyflo or Zyflo CR and changing to any formulary alternative would incur an unacceptable clinical risk to the patient (e.g., asthma patients stabilized on Zyflo).

Step 3 I certify the above is true to the best of my knowledge. Please sign and date:

3	_____ Prescriber Signature	_____ Date
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